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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/103,745	06/24/1998	SUDHIR AGRAWAL	475.08.642CI	3401
7590 01/24/2005				
WAYNE A KEOWN HALE AND DORR 60 STATE STREET BOSTON, MA 02109		EXAMINER SCHULTZ, JAMES		
		ART UNIT PAPER NUMBER		
		1635		

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/103,745

Applicant(s)

AGRAWAL, SUDHIR

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 3-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed November 5, 2004 adds new claims that are considered to be drawn to patentably distinct inventions. Accordingly, the claims of November 5, 2004 are subject to restriction as set forth below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I-X. Claims 1, 3-7, drawn to compounds and methods for inhibiting gene expression, wherein said compounds are drawn to modified oligonucleotides comprising modified CpG motifs, wherein said oligonucleotides are targeted to one of the following viral targets, each of which is placed in its own Group respectively: HIV, Epstein-Barr virus, Cytomegalovirus, respiratory syncytial virus, influenza virus, hepatitis B virus, hepatitis C virus, and papilloma virus, classified in class 514, subclass 44.
- XI-XV. Claims 1, 3-5, 8, and 9, drawn to compounds and methods for inhibiting gene expression, wherein said compounds are drawn to modified oligonucleotides comprising modified CpG motifs, wherein said oligonucleotides are targeted to one of the following prokaryotic targets: *Plasmodium falciparum*, *Plasmodium malarie*, *Plasmodium ovale*, *Schistosoma*, and *Mycobacterium tuberculosis*. classified in class 514, subclass 44.
- XVI-XXIV. Claims 1, 3-5, and 10-15, drawn to compounds and methods for inhibiting gene expression, wherein said compounds are drawn to modified oligonucleotides

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comprising modified CpG motifs, wherein said oligonucleotides are targeted to one of the following host targets: vascular endothelial growth factor, beta amyloid, DNA methyltransferase, protein kinase A, ApoE4 protein, p-glycoprotein, C-MYC protein, BCL-2 protein and CAPL, classified in class 514, subclass 44.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the multiple targets listed in the newly submitted claims are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434). Although nucleotide sequences are not currently being claimed, the claims recite different targets, wherein each is considered to encompass distinct and unique targets, and thus the reasoning supporting restriction of sequences applies herein.

Newly added claims 7, 9, 12, and 15 specifically claims oligonucleotides and methods of targeting a total of 24 distinct targets, wherein each target is not considered to be related by a common utility, and (2) a substantial structural feature disclosed as being essential to that utility. Although each target is claimed as being inhibited by modified CpG oligonucleotides, the inhibitory element of each oligonucleotide is derived from its sequence, not from the mere fact that each is an oligonucleotide. As such, the novelty of the inventions as restricted above is drawn to the sequence of the constituent nucleotides. Furthermore, such targets are considered to be structurally and functionally independent and distinct, because each comprises its own unique

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nucleotide sequence against which the claimed oligonucleotides must be designed. Each resulting oligonucleotide drawn to its distinct target will thus have its own unique sequence, and its own inhibitory profile, and each sequence would not render any other sequence obvious. Finally, a search for oligonucleotides against more than one of the targets as recited in the newly added claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed targets. In view of the foregoing, one (1) target is considered to be a reasonable number of targets for examination, and applicants are required to elect one (1) Group that corresponds to the elected target as set forth above.

Claims 1 and 3-6 link(s) the inventions of Groups I-X. Claims 1, 3-5 and 8, link the inventions of Groups XI-XV. Claims 1, 3-5, 11, 13, and 14 link(s) the inventions of Groups XVI-XXIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-

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9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JDS

A handwritten signature in black ink, appearing to read 'JD Schultz', with a long horizontal line extending to the right.

JD Schultz, PhD
Patent Examiner
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